CLAIMS

1. A compound which is a crystalline form II of esomeprazole magnesium trihydrate.

2. The compound of claim 1, having substantially the same X-ray diffraction pattern as shown in Figure 1.

3. The compound of claim 1, having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of about 4.824, about 5.552, about 7.411, about 8.608, about 12.104, about 14.16, about 18.471, and about 21.089.

4. The compound of claim 1, having an X-ray powder diffraction pattern expressed the terms of 2 theta angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 4.82±0.09, 5.55±0.09, 7.41±0.09, 8.60±09, 12.10±0.09, 14.16±0.09, 18.47±0.09, and 21.08±0.09.

5. The compound of claim 4, wherein the X-ray powder diffraction pattern includes peaks with 2 theta angles of about 4.82, about 5.55, about 7.41, about 8.60, about 12.10, about 14.16, about 18.47, and about 21.09.

7. A composition comprising esomeprazole magnesium, wherein at least 75% of said esomeprazole magnesium is a crystalline form II of esomeprazole magnesium trihydrate.

8. The composition of claim 7, which comprises at least 90% of said esomeprazole magnesium is the crystalline form II of esomeprazole magnesium.

9. The composition of claim 8, wherein at least 95% of said esomeprazole magnesium is the crystalline form II of esomeprazole magnesium.

10. The composition of claim 7, which is substantially free of other forms of esomeprazole magnesium.

11. The composition of claim 7, which is a solid powder of bulk esomeprazole magnesium for use as an active pharmaceutical ingredient.

12. The composition of claim 7, which has a moisture content of from about 2% to about 10% as measured by the Karl Fischer method.

13. The composition of claim 12, which has a moisture content of about 7% to about 8% as measured by the Karl Fischer method.

14. The composition of claim 7, wherein 20% or less by weight of the solid esomeprazole magnesium is in amorphous form.

15. The composition of claim 14, wherein 10% or less by weight of the solid esomeprazole magnesium is in amorphous form.

16. The composition of claim 14, wherein 5% or less by weight of the solid esomeprazole magnesium is in amorphous form.

17. The composition of claim 14, wherein 1% or less by weight of the solid esomeprazole magnesium is in amorphous form.

18. The composition of claim 14, wherein said solid esomeprazole magnesium is substantially free of the amorphous form of esomeprazole magnesium.

19. A process for making a trihydrate of esomeprazole magnesium in the form of a crystalline solid, said process comprising:

a) providing esomeprazole magnesium as a solution in a ketone-containing solvent;

b) cooling said solution so that a solid mass separates; and

c) isolating said separated solid mass, which is the trihydrate of esomeprazole magnesium in the form of a crystalline solid.

20. The process of claim 19, wherein said solution is provided by dissolving amorphous esomeprazole magnesium in said ketone-containing solvent.

21. The process of claim 20, wherein said amorphous esomeprazole magnesium is obtained by suspending magnesium metal in said alcohol-containing solvent in the presence of a haloalkane and adding esomeprazole base thereto.

22. The process of claim 21, wherein said alcohol-containing solvent is a mixture of alcohol and water.

23. The process of claim 21, wherein the alcohol-containing solvent includes an alcohol selected from the group consisting of methanol, ethanol, propanol, and butanol.

24. The process of claim 21, wherein the alcohol-containing solvent includes methanol.

25. The process of claim 21, wherein the haloalkane is selected from the group consisting of dichloromethane, trichloromethane, and dichloroethane.

26. The process of claim 21, wherein the haloalkane is dichloromethane.

27. The process of claim 19, wherein said ketone-containing solvent is a mixture of acetone and water.

28. The process of claim 27, wherein the amount of alcohol-containing solvent is about 5 ml to about 10 ml per 1 gram of the starting esomeprazole magnesium.

29. The process of claim 27, wherein the amount of water is about 5 ml to about 25 ml per 1 gram of the starting esomeprazole magnesium.

30. The process of claim 19, wherein the solid mass is isolated by filtration.

31. A process for making a trihydrate of esomeprazole magnesium in the form of a crystalline solid, said process comprising:

a) providing esomeprazole magnesium in methanol;

b) contacting said esomeprazole magnesium in methanol with water so that a solid mass separates;

c) isolating said solid mass by filtration;

d) washing said solid mass;

e) dissolving said solid mass in methanol and filtering the solution so formed to separate excess magnesium solids;

f) removing solvent from the solution to obtain isolated residual mass;

g) re-precipitating said isolated residual mass from a mixture of acetone and water, and

h) drying said isolated residual mass, which is the trihydrate of esomeprazole magnesium in the form of a crystalline solid.

32. The process of claim 31, wherein the esomeprazole magnesium is provided by suspending magnesium metal in methanol in the presence of dichloromethane and adding esomeprazole base.

33. A compound made by the process of claim 19.

34. A pharmaceutical composition comprising a crystalline form II of esomeprazole magnesium trihydrate and a pharmaceutically acceptable carrier.

35. A method for reducing gastric acid secretion in a subject which comprises administering to the subject an amount of a crystalline form II of esomeprazole magnesium trihydrate effective to reduce gastric acid secretion by said subject.

36. A method for reducing gastric acid secretion in a subject which comprises administering to the subject an amount of a crystalline form II of esomeprazole magnesium trihydrate effective to reduce gastric acid secretion by said subject.